ATSDR's Concept Paper on Evaluating Radiological Data From EPA's Florida Phosphate Mining Initiative

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Approaches to Radiological Evaluations

Background

On December 19, 2005, Dr. Howard Frumkin, Assistant Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR), and Jimmy Palmer, Regional Administrator of the Environmental Protection Agency (EPA) Region IV, discussed the EPA Florida Phosphate Initiative.

During this meeting, EPA asked ATSDR to prepare a concept paper describing the approach ATSDR would take if asked by EPA or the State of Florida to evaluate the radiological data from the Florida Phosphate Mining Initiative. The approach would not be implemented until ATSDR receives a request form EPA or the State of Florida to evaluate data.

Differences between EPA and ATSDR mandates

EPA

- Is mandated by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) to respond directly to releases or threatened releases of hazardous substances that might endanger public health or the environment.
- Is authorized to clean up abandoned or uncontrolled hazardous waste sites.
- Uses CERCLA risk limits to protect human health and the environment.

ATSDR

- Is mandated by Congress to determine whether
  - — Adverse human health affects may be expected at the observed levels of exposure or radiation dose.
  - — Actions should be taken to reduce human exposure.
  - — Additional information on human exposure and associated health risks is needed and should be acquired by means such as
    - conducting epidemiologic studies,
    - establishing an exposure registry, and
    - conducting health surveillance programs.
- Does not set clean-up levels.
- Focuses on observable health effects, rather than theoretical risk.

Differences between EPA and

EPA approach: risk assessments

- For ionizing radiation and other carcinogens, EPA uses CERCLA and the National Contingency Plan risk range of 10^{-4} to 10^{-6} excess cancer risk

ATSDR standards

above background levels, not dose, for clean-up decisions. This risk range is a theoretical construct that cannot actually be measured; in fact, the actual increase in cancer for some exposures could be as low as zero.

- A risk assessment is an analysis that uses information about toxic substances at a site to estimate a theoretical risk level for people who might be exposed to these substances. EPA uses risk assessment procedures to determine the need for remedial actions and to define how the cleanup should occur. A risk assessment does not measure the actual health effects that a site's hazardous substances have on people.
- To meet its mandates, EPA's risk assessments are intentionally conservative, and decision making usually relies on worst-case exposure assumptions.
- EPA response actions must comply with Applicable or Relevant and Appropriate Requirements (ARARs). For ionizing radiation, ARARs are defined by formalized legal standards (see table on page 6). The only ARAR that deals with radium in soil is the Uranium Mill Tailings Radiation Control Act.[1]

ATSDR approach: public health assessments

- ATSDR uses dose for health impact determinations. The agency uses risk assessments to decide whether further dose-based evaluations are needed.
- ATSDR's Division of Toxicology developed a minimal risk level (MRL) for exposure to ionizing radiation. This measure is the level below which adverse health effects are *not* expected to occur. MRLs account for uncertainty, thus enabling staff to rule out health concerns regarding estimated exposures below the MRL. The MRL has been peer reviewed and made available for public comment. MRLs consider interspecies (animal-to-human) variation and differences between humans.
- The chronic MRL for ionizing radiation is 100 mrem/year above background level. This is 15 times greater than EPA's theoretical upper limit of excess cancer risk of 10^{-4} (i.e., would result in a theoretical risk of about 1.5×10^{-3}).
- ATSDR has also developed an acute MRL of 400 mrem/yr for ionizing radiation, but this measure is not expected to be relevant for the longer-term exposure situation in Florida.
- ATSDR does not add organ specific doses, such as the lung dose from radon to the whole-body dose from gamma radiation exposure. For ATSDR's mandate, it is inappropriate to add these doses, because they lead to different health endpoints. However, for EPA's mandate, it may be appropriate to add the doses for triage of action, risk management, or remediation decisions.
- If EPA's risk assessments are within the acceptable risk range or if contaminant levels are below regulatory or recommended levels, ATSDR

[1]Environmental Protection Agency. Health and environmental standards for uranium and thorium mill tailings (UMTRCA), 40 C.F.R. 192. Washington, DC: Environmental Protection Agency; 1993.

usually reviews the assessment and quickly and confidently determines that no health effects are likely from the observed exposure levels.

- If, however, exposures are above risk levels considered safe by EPA or above recommended exposure levels, observable health effects cannot be assumed. ATSDR does a more intensive evaluation that is based on site-specific factors. ATSDR reviews the toxicologic, medical, and epidemiologic literature to determine if health effects have been shown, or are likely to occur, at the observed dose.

Agency radiation standards or guidelines

A variety of radiation standards or guidelines are used by other federal agencies and radiation protection committees. These are described in the following table.

Agency/ Organization	Standard (above background level)	Reference	Risk per 30 years*	Exceeds EPA upper risk range (10^{-4}) by a factor of…
OSHA, NRC, DOE	5,000 mrem/yr (worker)	29 CFR 1910; 10 CFR 20; 10 CFR 835	7.5×10^{-2}	750
NRC	100 mrem/yr (public)	10 CFR 20.1301	1.5×10^{-3}	15
DOE	100 mrem/yr (public)	10 CFR 835.208	1.5×10^{-3}	15
ATSDR	100 mrem/yr (public)	Toxicological Profile for Ionizing Radiation (Chronic MRL)	1.5×10^{-3}	15
EPA	10 mrem/yr (air pollution) (public)	NESHAPS 40 CFR 61	1.5×10^{-4}	1.5
ICRP	100 mrem/yr; or if >100, not to exceed an average of 100 mrem/5 yrs (public)	ICRP Publication 60	1.5×10^{-3}	15
NCRP	100 mrem/yr continuous exposure (public)	NCRP Report 116	1.5×10^{-3}	15
NCRP	360 mrem/yr from background (public)	NCRP Report 116	5.4×10^{-3}	54

*Based on a fatal cancer risk of 0.0005 per rem risk. The EPA default exposure duration is 30 years (Risk Assessment Guidance, Part B).

Abbrev: OSHA=Occupational Safety and Health Administration; NRC=Nuclear Regulatory Commission; DOE=Department of Energy; mrem/yr=millirem per year]; MRL=minimal risk level; NESHAPS=National Emissions Standards for Hazardous Air Pollutants; CFR=Code of Federal Regulations; ICRP=International Commission on Radiological Protection; NCRP=National Council on Radiation Protection and Measurements.

Other EPA standards: potential ARARs

The Government Accounting Office (GAO) reported in 1994 that, even within the EPA-CERCLA risk structure, EPA does not regulate radioactive materials equally across the board.

The following table, adapted from the GAO report, shows that the EPA carcinogenic upper risk range is exceeded in the case of indoor radon and uranium mill tailings or wastes generated by nuclear plant operations. It appears that limited public exposure to the associated radiation was considered when EPA set these limits. However, EPA risk calculations are difficult to compare, because they appear to use different cancer slope factors (see second footnote on the following table).

Table adapted from the Government Accounting Office (GAO)/Resources, Community, and Economic Development, Report 94-190, "Consensus on Acceptable Radiation Risk to the Public is Lacking"*

EPA regulation	Limit	Estimated lifetime risk (70 years)	Risk per 30 years	Exceeds EPA upper risk range by a factor of…
Indoor radon	4 pCi/L	2.5×10^{-2}	1.1×10^{-2}	110
Uranium mill tailings – radium	5 pCi/g	2.0×10^{-2}	8.6×10^{-3}▪	86
Uranium fuel cycle	25 mrem/yr	1.0×10^{-3}	4.3×10^{-4}	4.3
Spent fuel, transuranic wastes	15 mrem/yr	5.0×10^{-4}	2.1×10^{-4}	2.1

*GAO used a cancer risk coefficient of 0.0005 per rem per year and a lifetime equal to 70 years to calculate lifetime risk. ATSDR multiplied the GAO reported risk value by 30/70 to estimate the 30-year risk for comparison to the previous table.

▪The value calculated from the 1993 GAO report does not match EPA's risk calculation in the table on page 12.

Abbrev: pCi/L=picocurie per liter; pCi/g=picocurie per gram; mrem/yr=millirem per year.

Remediation Decisions

Potential steps in evaluating exposure

On the basis of discussions with EPA, ATSDR has determined that the following steps will be used in the Florida Phosphate Initiative evaluation.

Step	Action	Comment
1	Propose clean-up level	ATSDR will say if protective; likely "Yes" based on proposed 5 pCi/g
2	Aerial survey/flyover of area	ATSDR agrees with EPA
3	Follow up with scanner van in areas with high radiation exposure	ATSDR agrees with EPA
4	Manual survey: a hand-held survey for gamma radiation and radon of homes and lots identified by scanner van	ATSDR agrees with EPA
5	Setting the remedial action level	ATSDR should not participate (see below)
6	Remediation	ATSDR should not participate (see below)
7	Evaluation of sampling data	ATSDR can review data quality and decide whether it is sufficient. If requested, ATSDR can offer its opinion on whether health effects are likely at observed concentrations and exposure levels.

Step 1: Propose clean-up level

ATSDR does not have the regulatory or legislative authority to set clean-up levels. If requested by EPA or the State of Florida, ATSDR will evaluate environmental data and proposed clean-up levels to determine if the levels are protective of public health.

This determination will be based on current knowledge in the medical, toxicologic, and epidemiologic literature. If the proposed cleanup level is 5 pCi/g of radium in soil, ATSDR will likely concur that this level is protective of public health.

Step 2: Aerial survey

ATSDR concurs with EPA that an aerial survey for elevated radium concentrations would be prudent. The region has a history of strip mining for phosphate ore that is associated with elevated levels of naturally occurring radium. Phosphate mining can result in higher than normal concentrations of radioactive radium near the surface that can be mapped by aerial over-flights.

Step 3: Scanner van

ATSDR concurs that it would be prudent for EPA to follow up the aerial surveys with their radiation scanner van in areas of elevated radium contamination.

Step 4: Manual survey

ATSDR concurs that it would be prudent for EPA to follow up scanner van surveys with manual surveys of residences for radium contamination in yards and buildings and for indoor radon.

Step 5: Setting the remedial action level

The decision about when to clean up the site is potentially controversial. This paper gives additional information about the issues and approaches that EPA Headquarters, EPA Region IV, the State of Florida, and ATSDR have concerning the Florida Phosphate Mines. Discussion on approaches and factors impacting this decision is in the next section which starts on page 10.

The EPA documents are not clear about whether some of the calculated risks or soil concentrations are a) limits used to decide that a property will be cleaned up or b) levels to which properties will be cleaned when a decision to remediate has been made. Possible limits that might trigger a cleanup include the following:

- EPA Headquarters (HQ): 5 pCi/g soil above background level
- EPA Region IV: 5pCi/g soil, the CERCLA theoretical risk range of 1×10^{-4} to 1×10^{-6}
- Florida: 500 mrem/yr — a dose-based approach[2]
- ATSDR: The agency can comment on the protectiveness of a proposed clean-up level, but it **should not participate in the decision of when to clean up.** (See page 12 for factors affecting this decision.)
    - — ATSDR staff calculated that the concentration of radium in soil could be *more than 2* orders of magnitude higher than 5pCi/g and not exceed the chronic MRL of 100 mrem/yr.

[2] ATSDR. Public health assessment for Stauffer Chemical in Tarpon Springs, Florida. Prepared by the Florida Department of Health through a cooperative agreement with ATSDR. Atlanta, GA: US Department of Health and Human Services; 1993.

— ATSDR's review of the literature indicated that the dose could be 10 times greater than the 500 mrem/yr dose before adverse health effects are noted (the *lowest observed adverse effect level in humans is greater than 5 rem*[3]).

Step 6: Remediation

ATSDR can comment on proposed cleanup levels, but should not be involved with the actual cleanup or the remedial action level.

Step 7: Evaluation of sampling data

ATSDR can review data quality and determine whether it is sufficient. If requested, ATSDR can offer its opinion on whether health effects are likely at observed concentrations and exposure levels.

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[3] ATSDR. Toxicological profile for ionizing radiation. Atlanta, GA: US Department of Health and Human Services; 1999.

Determining the Need for Site Cleanup

Using land-use scenarios

Factoring in current land use and potential land development provides greater flexibility for step 5 in developing measures protective of human health. Different remedial action levels and clean-up goals depend on current or potential future land use. Land use will also impact the duration and frequency of exposures used in step 7 for the dose-based approach in evaluating adverse health effects resulting from exposure.

Unoccupied areas

If requested, ATSDR could comment on the protectiveness of remedial efforts with regard to

- Potential land use scenarios.
- Site-specific information affecting frequency and dose of exposure.

ATSDR agrees that clean-up levels that comply with the federal guidelines are protective of public health. In this case, the allowable limit under the Uranium Mill Tailings Radiation Control Act of 1978 is 5 pCi radium per gram of soil.

Residential homes—exposure below EPA action level

Safety factors are built into EPA's recommended exposure limits, so ATSDR would likely recommend no activities, with the exception of possible health education.

Residential homes—exposure above EPA action level

Determination of expected health effects: Further evaluation would be required. Because recommended exposure limits have safety factors incorporated, ATSDR would need additional resident-specific data to determine if occupants have been exposed at levels expected to have health implications.

- Even if an exposure is above an EPA action level but below a level at which adverse health affects might occur, ATSDR always agrees that reducing exposure to the lowest practical level is prudent public health practice.
- ATSDR evaluates whole-body dose and organ-specific dose depending on the isotope and pathway of concern.

Determination of future remediation requirements: ATSDR does not determine clean-up levels.

Determination of protectiveness of proposed clean-up levels: If requested,

ATSDR will evaluate whether a proposed clean-up level is protective of public health.

Community involvement and health education: Community involvement and notification will be crucial throughout the process. A health education program will probably be needed as well.

Using dose: the Florida approach

Based on ATSDR and EPA experience, Florida may prefer clean-up decisions based on actual dose measurement rather than theoretical risk. The following table lists conclusions each agency may reach using Florida's suggested approach (i.e., dose).

Dose	Agency conclusion
<100 mrem/yr (above background)	EPA: Action required. The theoretical excess cancer risk is 1×10^{-3}; therefore, values greater than the CERCLA incremental risk range of 10^{-4} to 10^{-6} is above background. Florida: No action required. ATSDR: Adverse health effects are not expected to occur.
100–500 mrem/yr (above background)	EPA: Action required. The theoretical excess cancer risk would range from 1×10^{-3} to 7×10^{-3}. Florida: Mitigate risk through education ATSDR: Above MRL; need site-specific information.
>500 mrem/yr (above background)	EPA: Remediate or potentially relocate. The theoretical excess cancer risk is greater than $2.5 \times 10^{-2.}$ Florida: Remediate. ATSDR: Above MRL; need site-specific information.
Dose from background	The average background for radiation, including radon, in the United States is 360 mrem/yr. The risk calculation for normal background exceeds the CERCLA risk range. The excess cancer risk from background is $1.2 \times 10^{-2.}$

Using soil concentration: the EPA approach

Both EPA Headquarters and EPA Region IV listed 5 pCi/g over background for radium-226 as an ARAR. It is unclear whether all properties >5 pCi/g would be required to be cleaned up to this level. The following table lists conclusions each agency might reach using 5 pCi/g over background as an action level for radium-226.

Agency	Conclusion
EPA	Equals a carcinogenic excess cancer risk of 4×10^{-4}, which exceeds the CERCLA risk range of 1×10^{-4} to 1×10^{-6}. (See note ▪ on page 6)
Florida	Would likely consider level overly conservative.
ATSDR	Considers 5 pCi/g protective of public health. This level should be the average of a large sampling area. **Note:** ATSDR's opinion is that the level could be higher. Using Federal Guidance Document 13 for Ra-226 in soil volumes, we calculated that the concentration of radium in soil could be more than 2 orders of magnitude higher and not exceed the chronic MRL of 100 mrem/yr.

Factors affecting the decision to cleanup

Many factors, in addition to health, impact the decision whether to clean up a contaminated area. These factors include the

- theoretical risk, including the risk from background
- location and type of contamination
- technical feasibility
- long-term effectiveness
- cost and available resources
- acceptance of the proposed remedy by the public
- economic effects
- ecologic effects
- lifestyle impact.

Note: ATSDR staff members do not have the necessary experience in evaluating cost benefits, ecologic benefits, or economics of site remediation.

EPA's Soil Clean-up Level Goal

The basis of the 5 pCi/g level

The proposed clean-up level of 5 pCi radium/g of soil (5 pCi/g) is based on EPA regulations stated in 40 CFR 192 as it pertains to uranium mine/mill sites. Although these sites are exempt from CERCLA, OSWER Directive 9200.4-25 indicates the 5 pCi/g can be used as an ARAR. The 5 pCi/g limit is based primarily on the assumption that radon decay products will reach equilibrium concentrations in homes built on the contaminated soil.

Impact of levels >5 pCi/g

ATSDR's determination is that the level could be higher. On the basis of EPA's Federal Guidance Document 13 for Ra-226 in soil volumes, ATSDR staff calculated that the concentration of radium in soil could be more than 2 orders of magnitude higher and not exceed the chronic MRL of 100 mrem/yr.

Protective effect of 5 pCi/g goal

On the basis of ATSDR's information, 5 pCi/g radium in soil should be protective of exposure to both radium and its decay product, radon. However, a closer evaluation of the homes with the highest level may be prudent to rule out other exposures.

Many cases exist where both EPA and ATSDR have used this level to ensure the safety of the public. ATSDR has used, and EPA concurred with, this value of 5 pCi/g at the following Superfund sites: Austin Avenue, Brown Vandever; Radium Chemical Company; H&K Aircraft Components; and D&L Sales.

Normal levels of radium in humans

The human body normally contains about 31 pCi of radium-226 as a result of water and food ingestion.

- Humans typically ingest 2.3 pCi of radium per day from food and water.
- Models indicate that the body absorbs 20% of radium ingested.

Bioassay Capabilities

NCEH laboratory readiness for bioassays of radium in humans

CDC's National Center for Environmental Health/Division of Laboratory Services (NCEH/DLS) does not have a method for analyzing radium-226 and cannot start to develop a method for radium-226 in urine for 2 years.

- ATSDR staff inquired about bioassays with James Pirkle, NCEH/DLS, John Osterloh from NCEH/DLS, and Elizabeth Southerland from EPA.
- The NCEH/DLS radiology laboratory component has been working full time on developing analytical methods for several other radionuclides that are a priority for the Department of Homeland Security for dirty bomb analyses.
- Dr. Pirkle expressed an interest in doing a study in the Florida phosphate mine area but said they could not do so at this time.